July 17, 2018

Public Testimony to US EPA

RE: Proposal to "Strengthen Transparency in Regulatory Science"

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My name is Albert Donnay, and my comments are based on experience gained from over 40 years of working on regulatory science as an environmental health engineer and toxicologist, as a research scientist, public health activist, clinician, consultant, and peer-reviewer for academic journals, environmental groups, and government agencies at all levels, including EPA.

EPA's proposal to "Strengthen Transparency in Regulatory Science" does not include any examples of regulations that have been undermined by a lack of such transparency, so I'd like remind to everyone of what is at stake, and what happened the first time EPA, Congress and environmental groups had to decide whether it was ok to base regulatory standards on published scientific studies whose archives were no longer available for review. They got the answer right then, and I hope they'll get it right again now.

It was May 1983, and EPA was about to publish a new NAAQS for carbon monoxide based on 9 studies by a distinguished cardiologist at the VA, Dr. Aronow, when the Washington Post reported that he had been barred by FDA a year earlier for submitting a "wave of false medical experiments" after he admitted "fudging" his lab reports in human drug studies. Although EPA's head of Air Quality Planning and Standards said the agency had "no reason to believe anything was wrong" with Aronow's CO studies--whose data Aronow claimed "Are excellent and can't be questioned"--EPA nevertheless appointed a special team of agency and outside scientists to review his work "when we read that Aronow had done some kooky things."

A month later, the Post reported the shocking results under the headline "EPA Probe criticizes a study used in air-quality standard." The team "could not resolve the issue of possible falsification of data" because "no data were available"--Aronow told them he had discarded the archives of all his CO studies after first storing them in his garage and then offering it to EPA because "they didn't want it."

The investigators noted "considerable concerns about the validity of the results reported.... Raw data were lost or discarded, adequate records were not maintained, available data were of poor quality, quality control was non-existent"--while Aronow's published results were consistently too good to be true. They found it "rather remarkable" that in 10 years of research his papers showed "not even one missing data point." They concluded that EPA "cannot rely on Dr. Aronow's data due to the

concerns we have noted" and recommended that the agency commission new research to attempt to replicate Aronow's findings. Congressional hearings and a GAO investigation followed, after which Administrator Ruckelshaus agreed that EPA would not rely on any of Aronow's studies in future rulemakings, but only on studies whose archives were still available for review.

In coordination with the California air Resources Board and the Health Effects Institute, EPA commissioned a series of new controlled human exposure studies on CO. and since 1994 has based the CO NAAQS exclusively on just 6 of them, all of which published their individual results in de-identified form so they would be available for public review in perpetuity. And it is a good thing they did since all the larger archives of these studies were eventually discarded by their authors without being offered to EPA. This history shows that EPA can and should base regulations solely on studies whose methods and data are available for review.

To base regulations on studies that can't be re-analyzed is not science and there is no need for it. Even federal rules that are based only on older epidemiology studies–like the last PM NAAQS rule in 2013 that cited just six—could and should be based on more recent research that better reflect current air quality. Over 500 studies a year are now published on particulate epidemiology and many are in high quality journals that require authors to make all their de-identified data and methods available-- at least to reviewers if not to all readers via the posting of supplemental material.

Given EPA's interest in basing regulations on more transparent research, EPA should start requiring all of the researchers it funds, both intramural and extramural, to publish their results in such journals. Hopefully this will prompt less rigorous journals that don't require the posting of supplemental material to update their policies.

The Aronow scandal shows EPA cannot rely exclusively on traditional peer-review to detect misconduct. He duped reviewers at 11 leading journals as well as EPA staff and their scientific advisors on the CASAC who also reviewed his studies before recommending that 9 be cited as the basis for the CO NAAQS. Unfortunately, despite all this publicity, none of Aronow's CO studies were retracted and EPA has started citing them again, most recently in its 2010 Integrated Science Assessment of the CO literature. EPA's proposal to strengthen transparency in regulatory science could stop this from happening again, which is why I support it and encourage my colleagues to do so as well.

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